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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/036,959	01/02/2002	David L. Hallahan	CL1792 US NA	4565

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EXAMINER	
KERR, KATHLEEN M	

ART UNIT	PAPER NUMBER
1652	

DATE MAILED: 10/03/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/036,959	HALLAHAN ET AL.	
	Examiner	Art Unit	
	Kathleen M Kerr	1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *02 July 2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-28* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-28* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Application Status

1. Claims 1-28 are pending in the instant application.

Restriction

2. Restriction to one of the following inventions is required under 35 U.S.C. § 121:

I. Claims 1, 2, 5, 10-14, 17 and 27, drawn to nucleic acid molecules related to a sequence encoding SEQ ID NO:8, a acetyl-CoA acetyltransferase, and related products, classified in class 435, subclass 193.

II. Claims 1, 2, 6, 10-14, 17 and 27, drawn to nucleic acid molecules related to a sequence encoding SEQ ID NO:9, a HMG-CoA synthase, and related products, classified in class 435, subclass 193.

III. Claims 1, 2, 7, 10-14, 17 and 27, drawn to nucleic acid molecules related to a sequence encoding SEQ ID NO:11, a mevalonate kinase, and related products, classified in class 435, subclass 194.

IV. Claims 1, 2, 8, 10-14, 17 and 27, drawn to nucleic acid molecules related to a sequence encoding SEQ ID NO:12, a phosphomevalonate kinase, and related products, classified in class 435, subclass 194.

V. Claims 1, 2, 9-14, 17 and 27, drawn to nucleic acid molecules related to a sequence encoding SEQ ID NO:13, a mevalonate diphosphate decarboxylase, and related products, classified in class 435, subclass 232.

VI. Claims 3-4, drawn to polypeptides related to SEQ ID NO:8, an acetyl-CoA acetyltransferase, classified in class 435, subclass 193.

VII. Claims 3-4, drawn to polypeptides related to SEQ ID NO:9, an HMG-CoA synthase, classified in class 435, subclass 193.

VIII. Claims 3-4, drawn to polypeptides related to SEQ ID NO:11, a mevalonate kinase, classified in class 435, subclass 194.

IX. Claims 3-4, drawn to polypeptides related to SEQ ID NO:12, a phosphomevalonate kinase, classified in class 435, subclass 194.

X. Claims 3-4, drawn to polypeptides related to SEQ ID NO:13, a mevalonate diphosphate decarboxylase, classified in class 435, subclass 232.

XI. Claims 15-16, drawn to methods of obtaining a nucleic acid related to a polynucleotide encoding SEQ ID NO:8, a acetyl-CoA acetyltransferase, classified in class 435, subclass 6.

XII. Claims 15-16, drawn to methods of obtaining a nucleic acid related to a polynucleotide encoding SEQ ID NO:9, a HMG-CoA synthase, classified in class 435, subclass 6.

XIII. Claims 15-16, drawn to methods of obtaining a nucleic acid related to a polynucleotide encoding SEQ ID NO:11, a mevalonate kinase, classified in class 435, subclass 6.

XIV. Claims 15-16, drawn to methods of obtaining a nucleic acid related to a polynucleotide encoding SEQ ID NO:12, a phosphomevalonate kinase, classified in class 435, subclass 6.

XV. Claims 15-16, drawn to methods of obtaining a nucleic acid related to a polynucleotide encoding SEQ ID NO:13, a mevalonate diphosphate decarboxylase, classified in class 435, subclass 6.

XVI. Claims 18-21, drawn to methods of obtaining a compound using SEQ ID NO:1 that encodes an acetyl-CoA acetyltransferase, classified in class 435, subclass 136.

XVII. Claims 18-21, drawn to methods of obtaining a compound using SEQ ID NO:2 that encodes an HMG-CoA synthase, classified in class 435, subclass 136.

XVIII. Claims 18-21, drawn to methods of obtaining a compound using SEQ ID NO:4 that encodes a mevalonate kinase, classified in class 435, subclass 136.

XIX. Claims 18-21, drawn to methods of obtaining a compound using SEQ ID NO:5 that encodes a phosphomevalonate kinase, classified in class 435, subclass 136.

XX. Claims 18-21, drawn to methods of obtaining a compound using SEQ ID NO:6 that encodes a mevalonate diphosphate decarboxylase, classified in class 435, subclass 136.

XXI. Claims 22-26, drawn to methods of regulating isopentenyl diphosphate biosynthesis using SEQ ID NO:1 that encodes an acetyl-CoA acetyltransferase, classified in class 435, subclass 136.

XXII. Claims 22-26, drawn to methods of regulating isopentenyl diphosphate biosynthesis using SEQ ID NO:2 that encodes an HMG-CoA synthase, classified in class 435, subclass 136.

XXIII. Claims 22-26, drawn to methods of regulating isopentenyl diphosphate biosynthesis using SEQ ID NO:4 that encodes a mevalonate kinase, classified in class 435, subclass 136.

XXIV. Claims 22-26, drawn to methods of regulating isopentenyl diphosphate biosynthesis using SEQ ID NO:5 that encodes a phosphomevalonate kinase, classified in class 435, subclass 136.

XXV. Claims 22-26, drawn to methods of regulating isopentenyl diphosphate biosynthesis using SEQ ID NO:6 that encodes a mevalonate diphosphate decarboxylase, classified in class 435, subclass 136.

XXVI. Claim 28, drawn to a nucleic acid molecule of SEQ ID NO:3, encoding an HMG-CoA reductase, classified in class 536, subclass 23.6.

3. The inventions are distinct, each from the other because of the following reasons:

Groups I-V and XXVI are all related to each other because they each, separately, encode enzymes involved in isopentenyl diphosphate biosynthesis in *Hevea brasiliensis*. However, each of these Groups is distinct from the others because the structures of the nucleic acids are each distinct. No disclosure of any consensus sequence among all the disclosed polynucleotides is found in the specification. Thus, no generic structure of all the Groups is taught. Moreover, their functions are distinct, each from the other, because they each encode different proteins that catalyze different reactions using different substrates to produce different products. Thus, Groups I-V and XXVI are patentably distinct, each from the other. Because these inventions are distinct for the reasons given above and the search required for Group I is not required for Group II, for example, due to the distinct polynucleotide sequence search as well as the distinct text search using the encoded enzyme's name, restriction for examination purposes as indicated is proper.

Groups VI-X are related to each other as enzymes involved in isopentenyl diphosphate biosynthesis in *Hevea brasiliensis*. However, each of these Groups is distinct from the others because the structures of the proteins are each distinct. No disclosure of any consensus sequence among all the disclosed proteins is found in the specification. Thus, no generic structure of all the Groups is taught. Moreover, their functions are distinct, each from the other, because they each catalyze different reactions using different substrates to produce different products. Thus, Groups VI-X are patentably distinct, each from the other. Because these inventions are distinct for the reasons given above and the search required for Group VI is not required for Group X, for

example, due to the distinct sequence protein search as well as the distinct text search using the encoded enzyme's name, restriction for examination purposes as indicated is proper.

Groups XI-XV are related as methods of using polynucleotides encoding enzymes involved in isopentenyl diphosphate biosynthesis in *Hevea brasiliensis*. However, these methods are distinct from each other for the reasons cited above for the polynucleotides themselves.

Groups XVI-XX are related as methods of using polynucleotides encoding enzymes involved in isopentenyl diphosphate biosynthesis in *Hevea brasiliensis*. However, these methods are distinct from each other for the reasons cited above for the polynucleotides themselves.

Groups XXI-XXV are related as methods of using polynucleotides encoding enzymes involved in isopentenyl diphosphate biosynthesis in *Hevea brasiliensis*. However, these methods are distinct from each other for the reasons cited above for the polynucleotides themselves.

The nucleic acids of Groups I-V are related to the enzymes of Groups VI-X, respectively, by virtue of the fact that the nucleic acids encode the enzymes. The nucleic acid molecule has utility for the recombinant production of the enzyme in a host cell. Although the nucleic acids and the enzymes are related, they are distinct inventions because they are wholly different in structure and function. Moreover, the enzyme product can be made by other and materially distinct processes, such as purification from a natural source; and the nucleic acid product can be used for processes other than the production of enzyme, such as nucleic acid hybridization assays. Therefore, Groups I-V are patentably distinct from Groups VI-X. Because these inventions are distinct for the reasons given above and the search required for Group I is not required for Group VI, for example, restriction for examination purposes as indicated is proper. While Groups I and VI are identically classified under U.S. Patent Classification guidelines, to

search them together would present a search burden on the Examiner due to the extensive databases of non-patent literature. For example, claims in Group I, drawn to nucleic acids, must be searched not only in commercial amino acid sequence databases, but also in textual databases because isolated polypeptides are often disclosed without the benefit of sequence information although the amino acid sequence is inherently the same as the sequence claimed. Additionally, the nucleic acid sequences must be searched in distinct nucleic acid sequence commercial databases. Thus, Groups I-V and VI-X have been appropriately restricted on the basis of being both independent or distinct and presenting a search burden on the Examiner if they were to be searched together.

Groups I-V are related to Groups XI-XV, Groups XVI-XX, and Groups XXI-XXV as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (M.P.E.P. § 806.05(h)). In the instant case, the product can be used for a materially different process of using the product, such a recombinant production of the encoded enzyme followed by purification of the enzyme. This method is materially different from any of the claimed methods due to the focus on the protein, both its expression and purification. Thus, Groups I-V are patentably distinct from Groups XI-XV, Groups XVI-XX, and Groups XXI-XXV. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

The polypeptides of Groups VI-X are related to the methods of Groups XI-XV, Groups XVI-XX, and Groups XXI-XXV by virtue of the polynucleotides that encode the polypeptides and that are used in the methods. However, the polypeptides are neither used as substrates nor produced as products in any of the methods. Thus, Groups VI-X are patentably distinct from Groups XI-XV, Groups XVI-XX, and Groups XXI-XXV. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

The polypeptides of Groups VI-X are related to the nucleic acid of Group XXVI because the polypeptides are involved in isopentenyl diphosphate biosynthesis in *Hevea brasiliensis* and the nucleic acid of Group XXVI encodes a protein involved in isopentenyl diphosphate biosynthesis in *Hevea brasiliensis*. However, the polypeptides have distinct structures and functions with respect to the nucleic acid of Group XXVI. Thus, Groups VI-X are patentably distinct from Group XXVI. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

The methods of Groups XI-XV, XVI-XX, and XXI-XXV are all related as methods of using polynucleotides encoding polypeptides involved in isopentenyl diphosphate biosynthesis in *Hevea brasiliensis*. However, each of the sets of methods has distinct method steps using different reagents to product wholly distinct products. Thus, Groups XI-XV are patentably distinct from Groups XVI-XX are patentably distinct from Groups XXI-XXV. Because these inventions are distinct for the reasons given above and the search required for Group XI is not required for Group XVI or for Group XXI, for example, since the distinct methods steps are part

of the search query and these steps are different requiring searches that are not co-extensive, restriction for examination purposes as indicated is proper.

The methods of Groups XI-XV, XVI-XX, and XXI-XXV are all related to Group XXVI, drawn to a polynucleotide encoding HMG-CoA reductase involved in IPP biosynthesis, since the methods also use polynucleotides encoding polypeptides involved in isopentenyl diphosphate biosynthesis in *Hevea brasiliensis*. However, the polynucleotides in the methods are distinct, both structurally and functionally, from the polynucleotides in Group XXVI. Thus, the methods neither use the polynucleotides of Group XXVI as reagents nor produce them as products. Thus, Groups XI-XV, XVI-XX, and XXI-XXV are patentably distinct from Group XXVI. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

Notice of Possible Rejoinder

4. The Examiner notes that if product claims in any of Groups I-V are found directed to an allowable product, then process claims in any Groups XI-XXV, which are directed to processes of using the patentable product, previously withdrawn from consideration as a result of a restriction requirement, would now be rejoined pursuant to the procedures set forth in the Official Gazette notice dated March 26, 1996 (1184 O.G. 86; see also M.P.E.P. § 821.04, *In re* Ochiai, and *In re* Brouwer). Since process claims would be rejoined and fully examined for patentability under 37 C.F.R. § 1.104, Applicants are instructed to amend said claims as deemed necessary according to rejections made against the elected claims.

Conclusion

5. A complete response to the instant Office action must include an election of invention to be examined.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kathleen M Kerr whose telephone number is (703) 305-1229. The examiner can normally be reached on Monday through Friday, from 8:30am to 5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathupura Achutamurthy can be reached on (703) 308-3804. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

KMK
October 1, 2003